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| APPLICATION NO.                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO. |
|---------------------------------------|-------------|----------------------|--------------------------|------------------|
| 10/566,479                            | 04/04/2006  | Alain Lebet          | RGC-DUL-P2               | 5095             |
| 44702                                 | 7590        | 10/07/2009           | EXAMINER                 |                  |
| OSTRAGER CHONG FLAHERTY & BROITMAN PC |             |                      | HORNBERGER, JENNIFER LEA |                  |
| 570 Lexington Avenue                  |             |                      | ART UNIT                 | PAPER NUMBER     |
| Floor 17                              |             |                      | 3734                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/566,479             | LEBET, ALAIN        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | JENNIFER L. HORNBERGER | 3734                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 31 January 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-14 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 101***

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 10 is rejected under 35 U.S.C. § 101 because they appear to embrace more than one statutory class of invention. Claims which are intended to embrace both product or machine and process is precluded by language of 35 USC 101, which sets forth statutory classes of the invention in the alternative only.
3. Claim 10 appears to be directed to the apparatus, however claim 10 recites the method of attaching the sliding tube and cutting blades consists of the step of encasing the base of the cutting blades in a truncated revolution cone, and thus appear to be directed to a process. As such, claim 10 appears to embrace multiple statutory classes of invention which is prohibited (See Ex parte Lyell, 17 USPQ2d 1548 (1990)).

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

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7. Regarding claim 1, the phrase "likely to" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. For examination purposes, the limitation "likely to slide along the aspiration needle" will be treated as "capable of sliding along the aspiration needle. For examination purposes, the limitation "likely to cooperate with a second connection interface communicating with an inflation fluid supply device" will be treated as "able to cooperate with a second connection interface device communicating with an inflation fluid supply device".

1. Regarding claim 2, the phrase "sealing between a first and a second end of support tube and sliding tube" is indefinite. It is unclear whether the sealing is required to be between the first end of the support tube and the first end of the sliding tube as well as between the second end of the sliding tube and the second end of the support tube or if the sealing between the tubes may be located anywhere between the two ends. For examination purposes, the limitation will be treated as the sealing required to be located anywhere between the first and second ends.

2. Regarding claim 12, the phrase "likely to" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. For examination purposes, the limitation "likely to be closed by a rubber plug" will be treated as capable of being closed by a rubber plug.

3. Regarding claim 13, there is an inconsistency in the language of the preamble and that of body of the claim thus making their scope unclear. The preamble of claim 1 recites an "A device for positioning a guiding tube for nephroscope, using an aspiration needle, fitted with a needle sleeve and closing mandarin, used as a guiding means for an inflatable enlargement device equipped with a cuff filled with inflation fluid" with the aspiration needle only functionally recited, e.g. for guiding an inflatable enlargement device, thus indicating that the claims are directed to the subcombination, the device for positioning a guiding tube. However claim 13

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positively recites the closing mandarin and needle sleeve, as an element of the invention, e.g.

"the closing mandarin is of form memory type, whereas the needle sleeve comprises a removable part whose removal permits inserting the closing mandarin further into the needle sleeve and thereby forming an arrester elbow", thus indicating that the claims are directed to the combination of the inflatable enlargement device and the aspiration needle. As such it is unclear whether applicant intends the claims to be drawn to the combination or the subcombination.

Applicant is hereby required to indicate which, the combination (the aspiration needle and device for positioning a guiding tube) or subcombination (device for positioning a guiding tube) the claims are intended to be drawn and make the language consistent with this intent. For examination purposes, the claims will be considered as drawn to the subcombination the device for positioning a guiding tube.

4. Claims 10 is invalid under 35 USC 112, second paragraph, since a claim which purports to be both apparatus and process is ambiguous and therefore does not particularly point out and distinctly claim the subject matter of the invention. Ex parte Lyell, 17 USPQ2d 1548 (1990). In that claims 10 are directed to the process rather than the apparatus of claim 7, these claims will not be further treated on the merits thereof.

5.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 1, 2, 3, 8, 9, 11, 12, and 13 as understood are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. (US 5,009,659) in view of Dragan et al. (US 4,654,027).

Regarding claims 1 and 13, Hamlin et al. disclose a device for positioning a guiding tube for nephroscope, using an aspiration needle, fitted with a needle sleeve and a closing mandrin of form memory type, whereas the needle sleeve formed of a removable part whose removal permits inserting the closing mandrin further into the needle sleeve and thereby forming an arrester elbow, used as guiding means for an inflatable enlargement device equipped with a cuff filled with an inflation fluid, characterized in that said inflatable enlargement device is comprised of a sliding tube (16) likely to slide along the aspiration needle of a support tube (12), around which the cuff (20) is secured, surrounding the sliding tube (16), whose inner diameter is inferior to the inner diameter of the support tube (20) constituting an inflation fluid circulation space which communicates through a first orifice with the inside of the cuff (col. 3, ln. 17-20) and through a second orifice with a filling tube (49; col. 4, ln. 1-12), a first connection interface device (48) capable of cooperating with a second connection interface device communicating with an inflation fluid supply device, the support tube (12) being connected to the sliding tube (16) at the proximal end in a sealed manner in that the tubes are not in fluid communication with each other (col. 4, ln. 1-19), a first sliding tube end (22) sliding tube (16) comprising at least two cutting blades (23,62) making up a trocar and a second sliding tube end comprising a handling sleeve (28). Hamlin et al. fail to disclose a closing device connected to the first connection interface device (48). Dragan et al. disclose a valve assembly (110) or "closing device" for controlling flow of inflation fluid between a fluid source and the catheter. The valve assembly comprises a ball valve biased closed by a spring, the ball displaceable under pressure from the syringe or fluid source to allow fluid to flow past the ball and into the catheter. It would have

been obvious to one of ordinary skill in the art to modify the first connection interface of Hamlin et al. to include a valve assembly as suggested by Dragan et al. in order to control flow of inflation fluid between the fluid source and the catheter.

Regarding claim 2, Hamlin et al. as modified by Dragan et al. disclose that sealing is provided between the first and second ends of the sliding and support tubes in that the tubes are not in fluid communication with each other (col. 4, ln. 1-19). The claimed phrase "sealing is between a first and a second end of support tube and sliding tube is obtained by shrinkage or by positioning a centring plug between the sliding tube and the support, followed by a sealing process by introduction of weld by capillarity between the sliding and support tubes and the centring plug, or by overmoulding a sealing cylinder made of plastic materials" is being treated as a product by process limitation; that is sealing between a first and a second end of the support tube and the sliding tube. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Regarding claim 3, Hamlin et al. in view of Dragan et al. disclose the closing device is comprised of a ball type device whose ball (118) is pressed against a tapered seat by a spring (119), and which allows the inflation fluid of the supply device to flow towards the cuff but which prevents said inflation fluid from flowing back (col. 10, ln. 37 - col. 11, ln. 12).

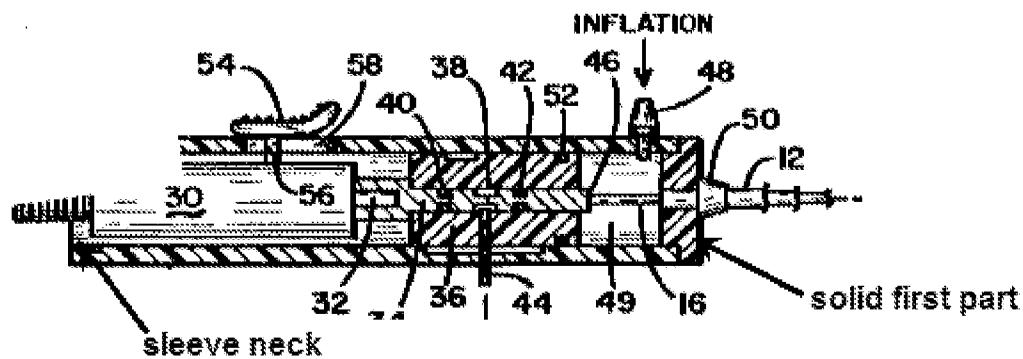
Regarding claim 8, Hamlin et al. as modified by Dragan et al. disclose the cutting blades (19, 46) are in the number of four to six (Fig. 2-5).

Regarding claim 9, Hamlin et al. as modified by Dragan et al. disclose the blades are attached to the sliding tube (16). The claimed phrase "an attachment process for the cutting

blades onto the sliding tube consists of laser welding" is being treated as a product by process limitation; that is the blades being attached to the sliding tube. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Regarding claim 11, Hamlin et al. as modified by Dragan et al. disclose a handling sleeve (28) covers the part of the sliding tube (16) which is located next to the second sliding tube end, the part of the support tube (12) and of the filling tube (49) located next to the second support tube end.

Regarding claim 12, Hamlin et al. as modified by Dragan et al. disclose a plastic handle sleeve (28; col. 4, ln. 2) with a first solid first part of sleeve (see figure below) covering a part of support tube (12), a second part of sleeve being hollowed in order to constitute the filling tube (49), ending by a sleeve neck (see figure below), open to the outside, and through which the sliding tube (16) passes, coaxially, and capable of being closed by a rubber plug. The claimed phrase "manufactured by overmoulding plastic material" is being treated as a product by process limitation; that is a plastic handle sleeve. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.



8. Claim 4 as understood is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. in view of Dragan et al. (US 4,654,027) as applied to claim 1 above, and further in view of Lary (US 4,273,128).

Dragan et al. disclose fail to disclose the first connection interface is a female cone, and a second connection interface (66) is comprised of a male cone which engages the female cone. Lary discloses a balloon catheter having a first connection interface comprising a female cone (11) and a second connection interface is a male cone for injecting inflation fluid into a balloon catheter. It would have been obvious to one of ordinary skill in the art to substitute the first connection interface member of Hamlin et al. in view of Dragan et al. with a female cone shaped interface member as suggested by Lary to achieve the same predictable result of mating connection interfaces for introducing fluid into the catheter.

Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

9. Claims 1 and 5 as understood are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. in view of Rauker (US 6,475,185). Hamlin et al. disclose a

device for positioning a guiding tube for nephroscope, using an aspiration needle, fitted with a needle sleeve and a closing mandrin of form memory type, whereas the needle sleeve formed of a removable part whose removal permits inserting the closing mandrin further into the needle sleeve and thereby forming an arrester elbow, used as guiding means for an inflatable enlargement device equipped with a cuff filled with an inflation fluid, characterized in that said inflatable enlargement device is comprised of a sliding tube (16) likely to slide along the aspiration needle of a support tube (12), around which the cuff (20) is secured, surrounding the sliding tube (16), whose inner diameter is inferior to the inner diameter of the support tube (20) constituting an inflation fluid circulation space which communicates through a first orifice with the inside of the cuff (col. 3, In. 17-20) and through a second orifice with a filling tube (49; col. 4, In. 1-12), a first connection interface device (48) capable of cooperating with a second connection interface device communicating with an inflation fluid supply device, the support tube (12) being connected to the sliding tube (16) at the proximal end in a sealed manner in that the tubes are not in fluid communication with each other (col. 4, In. 1-19), a first sliding tube end (22) sliding tube (16) comprising at least two cutting blades (23,62) making up a trocar and a second sliding tube end comprising a handling sleeve (28). Hamlin et al. fail to disclose a closing device connected to the first connection interface device (48). Rauker et al. disclose a balloon catheter having a rubber plug (36) or seal cooperating with a second connection interface device comprised of a needle (61) for introducing inflation fluid into the balloon catheter. It would have been obvious to one of ordinary skill in the art to modify the first connection interface of the device of Hamlin et al. to provide a plug to seal the port and prevent unwanted fluid from entering or escaping from the catheter.

10. Claim 6 as understood is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. in view of Dragan et al. (US 4,654,027) as applied to claim 1 above, and further in view of Kokernak (US 4,583,974).

Hamlin et al. in view of Dragan et al. a first a supply device is comprised of a syringe (25), featuring a cylindrical chamber (25a) in which a piston (27) slides. Hamlin et al. in view of a Dragan et al. fail to disclose a syringe with a control rod threaded and screwed into a nut of the syringe. Kokernak discloses a syringe (10) having a cylindrical chamber (14) in which a piston slides, and a control rod (20) threaded into a nut (12), solid within the chamber (Fig.1, 3). It would have been obvious to one of ordinary skill in the art to substitute the syringe of Hamlin et al. as modified by Dragan et al. with the syringe having a threaded rod as disclosed by Kokernak to achieve the same predictable result of a fluid source for injecting fluid into the catheter. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

11. Claim 7 as understood is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. in view of Dragan et al. (US 4,654,027) as applied to claim 1 above, and further in view of Vigil et al. (US 5,336,234).

Hamlin et al. as modified by Dragan et al. fail to disclose that the cutting blade has essentially triangular shape with a first blade side secured to the sliding tube along one of its generatrices, whereas a second blade side which includes a cutting thread forms an angle with the first blade side, whose top essentially coincides with the first sliding tube end, to the order of five to ten degrees. Vigil et al. disclose cutting blades (119) having a essentially triangular shape with a first blade side secured to a catheter along one of its generatrices, whereas a second blade side which includes a cutting thread forms an angle with the first blade side to the order of

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five to ten degrees. It would have been obvious to one of ordinary skill in the art to replace the blades of Hamlin et al. with elongated triangular blades to achieve the same predictable result of cutting through stenotic tissue. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

12. Claim 14 as understood is rejected under 35 U.S.C. 103(a) as being unpatentable over Hamlin et al. in view of Dragan et al. (US 4,654,027) as applied to claim 1 above, and further in view of Sahatjian (US 5,304,121).

Hamlin et al. in view of Dragan et al. fail to disclose that the outer surface of cuff is coated with a substance which becomes sticky at water contact in order to lubricate the cuff. Sahatjian discloses coating the surface of an angioplasty balloon with a hydrogel polymer for delivering a drug to plaque, and that hydrogel coating is advantageous because it prevents substantial release of the drug prior to reaching the treatment area (col. 4, ln. 41 - col. 5, ln. 60). Sahatjian discloses the surface of the balloon becomes lubricious upon exposure to water (col. 8, ln.9). It would have been obvious to one of ordinary skill in the art to modify the balloon of Hamlin et al. to include a hydrogel coating as suggested by Sahatjian for delivering drug to the plaque (26) at the treatment area.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jlh  
09/30/2009

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734